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WO 2004/037175 A3

(54) Title: COMPOSITIONS AND METHODS FOR TREATING HUMAN PAPILLOMAVIRUS-MEDIATED DISEASE

(57) Abstract: The invention includes methods of treating an HPV-mediated disease by administration to an individual of a pharmaceutical composition comprising a nucleic acid that encodes a polypeptide comprising an epitope of a naturally occurring HPV protein. The methods include the selection of individuals for treatment with the composition according to the age of the recipient, as well as the use of the composition to elicit a cross-reactive anti-HPV immune response.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/32705

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68

US CL : 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,306,397 B1 (EDWARDS et al) 23 October 2001 (23.10.2001), see the claims.	1, 2, 9-13
Y	KLENCKE et al. Encapsulated Plasmid DNA Treatment for Human Papillomavirus 16-associated Anal Dysplasia: A Phase I Study of ZYC101. Clinical Cancer Reseach. May 2002, Vol. 8, pages 1028-1037, see the abstract.	1, 2, 9-13
Y	MOSCICKI A.B. Human Papillomavirus Infection In Adolescents. Pediatric Clinics of North America. August 1999, Vol. 46, No. 4, pages 783-807, see page793.	1, 2, 9-13
Y	HEDLEY et al. Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nature Medicine. March 1998, Vol. 4, No. 3, pages 365-368, see the entire document.	1, 2, 9-13



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

14 April 2004 (14.04.2004)

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27 MAY 2004

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/32705

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claim Nos.: 16-50  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1, 2, 9-13

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Edwards et al (US Patent NO. 6,306,397 B1, October, 23, 2001) wherein the reference teaches a method of treating HPV is host (see claims 1, 2, 21, 32, and column 5, lines 58-65). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1, 2, 9-13, drawn to method of treating cervical intraepithelial neoplasia. (1<sup>st</sup> method)

Group II, claim(s) 3, 4, 9-15, drawn to method of treating human papillomavirus mediated disease. (2<sup>nd</sup> method)

Group III, claim(s) 5, 6, 9-13, drawn to method of selecting a treatment for an individual. (3<sup>rd</sup> method)

Group IV, claim(s) 7-13, drawn to kits. (1<sup>st</sup> product)

Group V, claim(s) 51, 52, 69-72, drawn to method of treating CIN. (4<sup>th</sup> method)

Group VI, claim(s) 53, drawn to method of treating CIN. (5<sup>th</sup> method)

Group VII, claim(s) 54, drawn to method of treating CIN. (6<sup>th</sup> method)

Group VIII, claim(s) 55, drawn to method of treating CIN. (7<sup>th</sup> method)

Group IX, claim(s) 56, drawn to method of treating HPV. (8<sup>th</sup> method)

Group X, claim(s) 57, drawn to method of treating HPV. (9<sup>th</sup> method)

Group XI, claim(s) 58, drawn to method of treating HPV. (10<sup>th</sup> method)

Group XII, claim(s) 59, drawn to method of treating HPV. (11<sup>th</sup> method)

Group XIII, claim(s) 60, drawn to method of treating HPV. (12<sup>th</sup> method)

Group XIV, claim(s) 61, drawn to method of selecting treatment (13<sup>th</sup> method).

Group XV, claim(s) 62, drawn to method of selecting treatment (14<sup>th</sup> method).

Group XVI, claim(s) 63, drawn to Kit. (2<sup>nd</sup> product)

Group XVII, claim(s) 64, drawn to Kit. (3<sup>rd</sup> product)

Group XVIII, claim(s) 65, drawn to Kit. (4<sup>th</sup> product)

Group XIX, claim(s) 66, drawn to Kit. (5<sup>th</sup> product)

Group XX, claim(s) 67, drawn to Kit. (6<sup>th</sup> product)

# INTERNATIONAL SEARCH REPORT

PCT/US03/32

Group XXI, claim(s) 68, drawn to Kit. (7<sup>th</sup> product)

**Continuation of B. FIELDS SEARCHED Item 3:**

MEDLINE, DERWENT, EPA, JAP, CAPLUS, NPL, WEST

Search terms: Papillomavirus, cervical intraepithelial neoplasia, CIN, treatm?, adolescent, young age